DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 14, 2015

SIEMENS HEALTHCARE DIAGNOSTICS
ASHA GARTLAND
TECHNICAL REGULATORY AFFAIRS SPECIALIST
511 BENEDICT AVENUE
TARRYTOWN NY 10591

Re: K150132
Trade/Device Name: IMMULITE® IGF Control Module
IMMULITE® Gastrin Control Module
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJX
Dated: January 19, 2015
Received: January 21, 2015

Dear Asha Gartland:

This letter corrects our substantially equivalent letter of April 13, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)
k150132

Device Name
IMMULITE® IGF Control Module
IMMULITE® Gastrin Control Module

Indications for Use *(Describe)*
IMMULITE® IGF Control Module is an assayed, bi-level control intended for use with IMMULITE/IMMULITE 1000 and IMMULITE 2000 IGF-I, and IMMULITE/IMMULITE 1000 and IMMULITE 2000 IGFBP-3 assays. It is intended as an aid in monitoring day-to-day assay performance.

IMMULITE Gastrin Control Module is an assayed, bi-level control intended for use with the IMMULITE/IMMULITE 1000 and IMMULITE 2000 Gastrin assay. It is intended as an aid in monitoring day-to-day assay performance.

Type of Use *(Select one or both, as applicable)*
X Prescription Use (Part 21 CFR 801 Subpart D) □Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SIEMENS

Section 006: 510(k) Summary

510(k) Summary

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: k150132

1. Submitter	
Mailing Address:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591
Contact Person:	Asha Gartland Technical Regulatory Affairs Specialist
Phone Number:	(914)-524-3257
Fax Number:	(914)-524-2101
E-mail Address:	asha.gartland@siemens.com
Date Prepared:	March 2nd, 2015
2. Device Name	
Proprietary Name:	**IMMULITE® IGF Control Module**
Regulation Section:	21 CFR 862.1660, Quality Control Material
Classification:	Class I Reserved
Products Code:	JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)
Panel:	Clinical Chemistry (75)
3. Predicate Device Name	IMMULITE® SHBG Controls
Predicate 510(k) No:	K955440
4. Device Description:	IMMULITE® IGF Control Module contains one set of 2 vials, each 4.0mL after reconstitution, containing lyophilized IGF-I and IGFBP-3 in a protein buffer matrix.
5. Intended Use:	See Indications for Use Statement below:
Indication for Use:	IMMULITE® IGF Control Module is an assayed, bi-level control intended for use with IMMULITE/IMMULITE 1000 and IMMULITE 2000 IGF-I, and IMMULITE/IMMULITE 1000 and IMMULITE 2000 IGFBP-3 assays. It is intended as an aid in monitoring day-to-day assay performance.
Special Conditions for Use Statement(s):	For prescription use only

Special Instrument Requirements: IMMULITE® 1000 and IMMULITE® 2000 Systems

6. Technological Characteristics and Substantial Equivalence Comparison with Predicate:

A comparison of the device features, intended use, and other information demonstrates that the IMMULITE® IGF Control Module is substantially equivalent to the predicate device as summarized in **Table 1**.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device IMMULITE IGF Control Module	Predicate Device IMMULITE SHBG Controls
Intended Use	IMMULITE IGF Control Module is an assayed, bi-level control intended for use with IMMULITE/IMMULITE 1000 and IMMULITE 2000 IGF-I, and IMMULITE/IMMULITE 1000 and IMMULITE 2000 IGFBP-3 assays. It is intended as an aid in monitoring day-to-day assay performance.	SHBG Controls are assayed, bi-level controls intended for use with the IMMULITE 2000 SHBG assay. They are intended as an aid in monitoring day-to-day assay performance.
Form	Lyophilized	Same
Stability	Stable unopened until the expiration date	Same
Levels	2	Same
Matrix	Bovine protein/buffer matrix with preservatives	Same

DIFFERENCES		
	Candidate Device IMMULITE IGF Control Module	Predicate Device IMMULITE SHBG Controls
Analyte(s)	IGF-I and IGFBP-3	SHBG
Storage	-20°C for 30 days after reconstitution (aliquotted)	2 -8 °C for 30 days after reconstitution or at -20°C for 6 months (aliquotted)

7. Non-Clinical Performance Testing

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intended use. The following tests were performed on the candidate device.

7.1 Stability Summary:

The stability study was conducted to validate real-time shelf life and open vial claim for the IMMULITE IGF Control Module to ensure that it maintains optimal product performance on IMMULITE 2000 platforms throughout the established shelf life of the control material before and after reconstitution.

The IMMULITE IGF Control Module is stable for up to 3 years from date of manufacture, when stored at 2 - 8 °C prior to opening. Stability, after opening and reconstitution, is for 30 days at –20°C, if aliquotted and frozen immediately.

7.1.1 Stability Protocol Summary:

The stability controls are run in duplicate (as a minimum) and the dose value determined from a 2-point adjustment at the time points as shown in **Table 2**. Stability controls are run every 6 months until expiry.

Table 2: Stability Time Points

IGF Control Module level	**Time-Points in Days (months)**						
IGF-I							
LGCOC1	1	182 (6 months)	365 (12 Months)	548 (18 months)	730 (24 months)	912 (30 months)	1095 (36 months)
LGCOC2	1	182 (6 months)	365 (12 Months)	548 (18 months)	730 (24 months)	912 (30 months)	1095 (36 months)
IGFBP-3							
LGCOC1	1	182 (6 months)	365 (12 Months)	548 (18 months)	730 (24 months)	912 (30 months)	1095 (36 months)
LGCOC2	1	182 (6 months)	365 (12 Months)	548 (18 months)	730 (24 months)	912 (30 months)	1095 (36 months)

For open vial testing, the results are determined from a 2-point adjustment. Using IGF Control Lot 024 a freshly opened vial was compared to a vial opened 35 days prior and stored at -20°C.

7.1.2 Stability Acceptance Criteria Summary:

The Acceptance Criteria for the IMMULITE IGF Control Module stability is summarized in **Table 3**.

Table 3 Acceptance criteria for stability of IMMULITE IGF Control lot 23

Level	Range	+/-% Acceptance Criteria
IMMULITE 2000 IGF-I (ng/mL)		
LGCOC10023	65 – 97	20
LGCOC20023	194 – 290	20
IMMULITE 2000 IGFBP-3 (µg/mL) kit lots 210 and below		
LGCOC10023	0.84 – 1.20	17.6
LGCOC20023	3.5 – 4.9	16.7
IMMULITE 2000 IGFBP-3 (µg/mL) kit lots 211 and above		
LGCOC10023	0.80 – 1.16	18.4
LGCOC20023	3.24 – 4.60	17.3

For open vial stability testing, the difference between the stored and the freshly opened vial dose value should be within ±10%.

7.2 Traceability:

The controls are used for quality control purposes only. Therefore traceability is not applicable for controls.

The IMMULITE controls are value assigned using assigned reference controls. The assigned reference controls are prepared using IGF-I and IGFBP-3 antigen stock. Human Recombinant IGF-I antigen and IGF-I/IGFBP-3 positive human serum are used.

7.3 Value Assignment:

The IMMULITE controls are value assigned using assigned reference controls. The assigned reference controls are prepared using IGF-I and IGFBP-3 antigen stock. The controls are manufactured using qualified materials and measurement procedures.

IGF controls are required to have a minimum of 100 control points from at least 3 kit lots and 3 instruments on both IMMULITE/IMMULITE 1000 and IMMULITE 2000 platforms and for both IGF-I and IGFBP-3. Both the controls being targeted (minimum 10 replicates) and the reference controls (2 replicates) are run together in each assay. Each assay is run using an adjusted curve. The control values are calculated based on the recovered values for each run on each instrument independently. Control values are then averaged across all systems. Validation of the value

assignment (quality control) is performed by calculating the recovery of patient samples and reference controls using the assigned control values. The reference controls must fall within their target ranges.

7.4 Expected Values

The controls must fall within their target ranges as shown in **Table 4**. Example of values from IGF control lot 0027.

Table 4 Control Target Range (lot 0027)

Control level	Mean	SD	2SD Range
IMMULITE/IMMULITE 1000 IGF-I (ng/mL) kit lots 401 and above			
LGCOC10027	91	9.1	73 - 109
LGCOC20027	277	27.7	222 - 332
IMMULITE 2000 IGF-I (ng/mL) kit lots 510-517			
LGCOC10027	75	7.5	60 - 90
LGCOC20027	239	23.9	191 - 287
IMMULITE 2000 IGF-I (ng/mL) kit lots 518 and above			
LGCOC10027	70	7.0	56 - 84
LGCOC20027	227	22.7	182 - 272
IMMULITE/IMMULITE 1000 IGFBP-3 (µg/mL) all kit lots			
LGCOC10027	1.10	0.12	0.86 – 1.34
LGCOC20027	4.4	0.40	3.6 – 5.2
IMMULITE 2000 IGFBP-3 (µg/mL) all kit lots			
LGCOC10027	0.98	0.09	0.80 - 1.16
LGCOC20027	3.8	0.32	3.2 - 4.4

Assay range:
IMMULITE 2000 IGF-I : up to 1600 ng/mL
IMMULITE 2000 IGFBP-3: up to 16 µg/mL

Each laboratory should establish their limits for acceptability based on methodology, clinical significance and medical decision levels of the test analyte. The representative, total precision tabulated in the respective assay instructions for use may be considered as one factor when

establishing local, acceptable ranges. The values provided above may be considered as guidelines. Value assignment is lot specific.

Standard/Guidance Documents Referenced**:**

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

Proposed Labeling**:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

8.0 Conclusion:

The IMMULITE® IGF Control Module is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the FDA cleared IMMULITE® SHBG Controls. The substantial equivalence of the device is supported by the non-clinical testing and was found to be comparable and supports the claims of substantial equivalence, product safety and effectiveness. Based on the testing completed and the comparisons with predicate device, the IMMULITE® IGF Control Module does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.

SIEMENS

510(k) Summary

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: k150132

1. **Submitter**

Mailing Address:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591
Contact Person:	Asha Gartland Technical Regulatory Affairs Specialist
Phone Number:	(914)-524-3257
Fax Number:	(914)-524-2101
E-mail Address:	asha.gartland@siemens.com
Date Prepared:	March 2nd, 2015

2. **Device Name**

Proprietary Name:	**IMMULITE® Gastrin Control Module**
Regulation Section:	21 CFR 862.1660, Quality Control Material
Classification:	Class I Reserved
Products Code:	JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)
Panel:	Clinical Chemistry (75)

3. **Predicate Device Name** — IMMULITE® 2000 SHBG Controls
   Predicate 510(k) No: K955440

4. **Device Description:** IMMULITE Gastrin Control Module contains one set of 2 vials, each 2.0mL after reconstitution, containing lyophilized synthetic-human G-17 gastrin in a buffer matrix.

5. **Intended Use:** See Indications for Use Statement below
   Indication for Use: The IMMULITE Gastrin Control Module is an assayed, bi-level control intended for use with the IMMULITE/IMMULITE 1000 and IMMULITE 2000 Gastrin assay. It is intended as an aid in monitoring day-to-day assay performance.

Special Conditions for Use Statement(s):	For prescription use only
Special Instrument Requirements:	IMMULITE® 1000 and IMMULITE® 2000 Systems

6. Technological Characteristics and Substantial Equivalence

Comparison with Predicate:

A comparison of the device features, intended use, and other information demonstrates that the IMMULITE® Gastrin Control Module is substantially equivalent to the predicate device as summarized in **Table 1**.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device IMMULITE® Gastrin Control Module	**Predicate Device IMMULITE® SHBG Controls**
Intended Use	The IMMULITE Gastrin Control Module is an assayed, bi-level control intended for use with the IMMULITE/IMMULITE 1000 and IMMULITE 2000 Gastrin assay. It is intended as an aid in monitoring day-to-day assay performance.	SHBG Controls are assayed, bi-level controls intended for use with the IMMULITE 2000 SHBG assay. They are intended as an aid in monitoring day-to-day assay performance.
Form	Lyophilized	Same
Levels	2	Same
Stability	Stable unopened until the expiration date	Same

DIFFERENCES		
	Candidate Device IMMULITE® Gastrin Control Module	**Predicate Device IMMULITE® SHBG Controls**
Analyte	Gastrin	SHBG
Matrix	Buffered matrix	Non-human (bovine) protein/buffer matrix
Storage	-20°C for 30 days after reconstitution (aliquotted)	2 -8°C for 30 days after reconstitution or at -20°C for 6 months (aliquotted)

7. Non-Clinical Performance Testing

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intended use. The following tests were performed on the candidate device.

7.1 Stability Summary:

The stability study was conducted to validate real-time shelf life and open vial claim for the IMMULITE Gastrin Control Module to ensure that it maintains optimal product performance on IMMULITE 2000 platforms throughout the established shelf life of the control material before and after reconstitution.

The IMMULITE Gastrin Control Module is stable for up to 3 years from date of manufacture, when stored at 2 - 8 °C prior to opening. Stability after opening and reconstitution, is for 30 days at –20°C, if aliquotted and frozen immediately.

7.1.1 Stability Protocol Summary:

The stability controls are run in duplicate (as a minimum) and the dose value determined from a 2-point adjustment at the time points as shown in **Table 2**. Stability controls are run every 6 months until expiry.

Table 2: Stability Time Points

Gastrin Control level	**Time-Points in Days (months)**						
LGAC1	1	182 (6 months)	365 (12 Months)	548 (18 months)	730 (24 months)	912 (30 months)	1095 (36 months)
LGAC2	1	182 (6 months)	365 (12 Months)	548 (18 months)	730 (24 months)	912 (30 months)	1095 (36 months)

For Open Vial testing, the results are determined from a 2-point adjustment. Using Gastrin Control Lot 030 a freshly opened vial was compared to a vial opened 35 days prior and stored at -20°C.

7.1.2 Stability Acceptance Criteria Summary:

The Acceptance Criteria for the IMMULITE Gastrin Control Module is summarized in **Table 3**.

Table 3 Acceptance criteria for stability of IMMULITE Gastrin Control lot 30

Control Level	Range	+/-% Acceptance Criteria
LGAC10030	85 – 113	14.0%
LGAC20030	341 – 453	14.2%

For Open Vial stability testing the difference between the stored and the freshly opened vial dose value should be within ±10%.

7.2 Traceability:

The controls are used for quality control purposes only. Therefore traceability is not applicable for controls.

The IMMULITE controls are value assigned using assigned reference controls. The assigned reference controls are prepared using qualified Gastrin antigen stock. Synthetic gastrin antigen is used.

7.3 Value Assignment:

The IMMULITE controls are value assigned using assigned reference controls. The assigned reference controls are prepared using qualified Gastrin antigen stock. The controls are manufactured using qualified materials and measurement procedures.

Gastrin controls are required to have a minimum of 100 control points from at least 3 kit lots and 3 instruments on both IMMULITE/IMMULITE 1000 and IMMULITE 2000 platforms. Both the controls being targeted (minimum 10 replicates) and the reference controls (2 replicates) are run together using an adjusted curve. The control values are assigned based on the recovered values for each run on each instrument independently. Control values are then averaged across all systems. The data is then reviewed for outliers (>3SD) and bi-modality or skewness within individual assays. Validation of the value assignment (quality control) is performed by calculating the recovery of patient samples and reference controls using the assigned control values. The reference controls must fall within their target ranges

7.4 Expected Values

The controls must fall within their target ranges as shown in **Table 3**. Example of values from Gastrin control lot 0035.

Table 3 Control Target Range (lot 0035)

Control Level	Mean	SD	2 SD Range
IMMULITE/IMMULITE 1000 Gastrin (pg/mL)			
LGAC10035	94	6.1	82 - 106
LGAC20035	364	29	306 - 422
IMMULITE 2000 Gastrin (pg/mL)			
LGAC10035	94	6.6	81 - 107
LGAC20035	363	25	313 - 413

IMMULITE 2000 Gastrin Assay Range = Up to 1,000 pg/mL

Each laboratory should establish their limits for acceptability based on methodology, clinical significance and medical decision levels of the test analyte. The representative, total precision tabulated in the respective assay instructions for use may be considered as one factor when establishing local, acceptable ranges. The values provided above may be considered as guidelines. Value assignment is lot specific.

Standard/Guidance Documents Referenced**:**

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

Proposed Labeling**:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

8. Conclusion:

The IMMULITE® IMMULITE Gastrin Control Module is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the FDA cleared IMMULITE® SHBG Controls. The substantial equivalence of the device is supported by the non-clinical testing and was found to be comparable and supports the claims of substantial equivalence, product safety and effectiveness. Based on the testing completed and the comparisons with predicate device, the IMMULITE® IMMULITE Gastrin Control Module does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.